UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
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Fax Cover Sheet

Date: 17 Sep 2004

To: HUESCHEN & SAGE	**From:** Ex. S. Devi, Ph.D.
Application/Control Number: 09/831,061	**Art Unit:** 1645
Fax No.: 269-382-2030	**Phone No.:** 571-272-0854
Voice No.: 269-382-0033	**Return Fax No.:** 703-872-9306
Re: Page 5 of 09/08/04 Office Action	**CC:**

☐ **Urgent** ☐ **For Review** ☐ **For Comment** ☐ **For Reply** ☒ **Per Your Request**

Comments:

As per your earlier telephone request, please find page 5 of the Office Action mailed 09/08/04 in application 09/831,061

Number of pages 2 including this page

Binz *et al.* disclose oligosaccharide antigens coupled to the P40 OmpA protein and the use of this P40 OmpA protein as a protein carrier of oligosaccharides for improving the immune response against an oligosaccharide antigen in a mammal. Applicants contend that Binz *et al.* does not disclose nor suggest that P40 OmpA is capable of binding to an APC and be internalized into the APC with the coupled active substance. Applicants submit that they have demonstrated in Example 6 and Figure 4 of the specification that other carrier proteins, such as TT or BB, are not capable of binding to APCs and thus are not internalized by APCs. Applicants conclude that the capability of a carrier to enhance an immune response to an associated antigen is not inherent in its capacity to bind APCs or to be internalized within these cells.

With regard to the disclosure of Andreoni *et al.*, Applicants contend that Andreoni *et al.* do not disclose nor suggest that P40 OmpA is capable of specifically binding to APCs and to be internalized by these APCs together with the active substance coupled with P40. Applicants allege that the Office has not identified a *prima facie* basis for an anticipation rejection. Applicants argue that the cited references do not disclose or suggest a method to specifically deliver an active substance into APCs by coupling the active substance with the P40 OmpA protein as claimed.

Applicants' arguments have been carefully considered, but are non-persuasive. It should be noted that the method claimed in the instant claims, as amended, does not require or include the step of 'internalization into the APC'. Furthermore, the instant claims do not require that the P40 OmpA specifically binds to APCs. With regard to the APCs, the only requirement is that the biologically active substance coupled to the OmpA having the structure of SEQ ID NO: 2 is 'contacted' with antigen-presenting cells, irrespective of whether the 'contacting' takes place *in vitro* or *in vivo*. The two references used in the art rejection taught the two required steps of the claimed method: a) covalently coupling a biologically active substance to the OmpA protein having the amino acid sequence of SEQ ID NO: 2 chemically, or recombinantly by genetic fusion; and b) contacting the coupled biologically active substance with antigen-presenting cells. Clearly, the Office has established a *prima facie* basis for anticipation.

New Rejection(s)

Applicants are asked to note the following new or modified rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments to the claims.

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*** TX REPORT ***
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